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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,717	01/13/2004	Edward L. Sinofsky	CFI-5755CONI	2652

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EDWARDS LIFESCIENCES CORPORATION  
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IRVINE, CA 92614

EXAMINER
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VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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08/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

.10/756,717

Applicant(s)

SINOFSKY, EDWARD L.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### **Terminal disclaimers filed.**

RCE filed 6-8-07.

The application is part of the following family of applications:

10/756,660; 10/756,717; 10/756,645; 10/756,014. The Applicant should submit and ensure that all four applications include terminal disclaimers toward each of the other applications. The below Double Patenting rejections request just that. For the sake of completeness all of the related applications are listed and as such, some of the Double Patenting rejections might have already been addressed.

The application is published application number: 2004/0147913.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish in view of Edwards 6,056,744.

#### Parentheticals and non-claim language refer to Koblish

1. A surgical ablation instrument (see figure 36-40 and relevant disclosure in col. 21:47 through col. 23:10) comprising: a housing (360 and 364) having a longitudinal lumen (370), the distal end of the housing being sufficiently flexible to be bent into a loop

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configuration (figures 36 and 39); an ablation element (372) disposable within (depicted in figure 38) the lumen of the housing to ablate tissue at a target site; and a fluid channel (376-370-374) within the housing for introducing fluid (from 378) to the ablation element during delivery of the ablation energy.

2. The instrument of claim 1, wherein the fluid (from 378) is delivered (374) between the ablation element (372) and the housing (364). See figures 37-38.

3. The instrument of claim 1, wherein the housing further includes a handle (18) portion at a proximal end.

4. The instrument of claim 3, wherein the handle portion includes a fluid inflow port (376, figure 38) and a fluid carrying lumen (370) for delivering the fluid to the housing (360 and 364).

5. The instrument of claim 1, wherein the distal end of the housing includes a fluid outflow port (374) for release of the fluid. Also note that 364 is porous.

6. The instrument of claim 1, wherein the fluid comprises a material (saline, col. 22:10), which cools the ablation element during delivery of ablative energy.

7. The instrument of claim 1, wherein the fluid is a lubricating fluid (saline, col. 22:10).

8. The instrument of claim 1, wherein the fluid comprises a physiologically compatible fluid (saline, col. 22:10).

9. The instrument of claim 8, wherein the fluid is saline (saline, col. 22:10).

10. A method for ablating a target tissue, comprising the steps of: providing a surgical ablation instrument comprising a housing having a proximal end, a distal end and a longitudinal lumen extending therebetween, the distal end of the housing being sufficiently flexible to be bent into a loop configuration, an ablation element disposed within the lumen of the housing to ablate tissue at a target site, and a fluid channel within the housing for introducing fluid to the ablation element during delivery of the ablation energy; positioning the surgical ablation instrument proximate to a predetermined tissue site; delivering ablative energy to said distal end of said housing through said ablation element, such that said target tissue is ablated without damaging surrounding tissue. All anticipated structure addressed prior. The anticipated structure yields the above method of use.

11. The method of claim 10, further comprising the step of introducing a fluid between the ablation element and the housing during the energy delivery. See col. 21:65 through col. 22:5.

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12. The method of claim 11, wherein the fluid comprises a material which cools the ablation element, and the step of introducing a fluid cools the ablation element during delivery of the ablative energy. See col. 21:65 through col. 22:15. The disclosure teaches the use of saline during the method of use to establish an electrically conductive path. The saline will inherently provide a cooling effect to the activated electrode.

13. The method of claim 11, wherein the fluid comprises a lubricating fluid, and the step of introducing a fluid lubricates the ablation element during delivery of the ablative energy. See col. 21:65 through col. 22:15. The disclosure teaches the use of saline during the method of use to establish an electrically conductive path. The saline will inherently provide a lubricating effect to the activated electrode.

14. The method of claim 11, further comprising the step of irrigating the target site by releasing the fluid from the housing into the target site. See col. 22:54-55, "low...liquid perfusion is preferred." This refers to irrigation of the target site, although minimal, from the housing (364).

15. The method of claim 10, further comprising the step of repeating the steps of positioning and delivering until a composite lesion of a desired shape is formed. The Office contends it inherent that the Koblish device would require, due to its looped structure, repeating steps of positioning and delivering to create the circumferential

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lesions in figure 34d. Need be, the Hall patent (6,652,517, figure 15, col. 2:51-55, *inter alia*) will be introduced to prosecution disclosing the literal language of repeated advancing and rotating of the ablation element to create a circumferential lesion.)

16. The method of claim 10, wherein the target site is cardiac tissue (see figure 34d).

17. A method for ablating a target tissue, comprising the steps of: providing a surgical epicardial (col. 20:64-67) ablation instrument comprising a housing having a proximal end, a distal end and a longitudinal lumen extending therebetween, the distal end of the housing being sufficiently flexible to be bent into a loop configuration an ablation element disposed within the lumen of the housing to ablate tissue at a target site, and a fluid channel within the housing for introducing fluid to the ablation element during delivery of the ablation energy; positioning the surgical ablation instrument proximate to a predetermined tissue site; delivering ablative energy to said distal end of said housing through said ablation element, such that said target tissue is ablated without damaging surrounding tissue. All anticipated structure addressed prior. The anticipated structure yields the above method of use.

Edwards' use in this rejection is elaborated in the Response to Arguments section.

### ***Double Patenting***

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of copending Application No. 10/756,660. Although the conflicting claims are not identical, they are not patentably distinct from each other because both groups of claims disclose a surgical ablation instrument with either a loop or disposable ablation element.



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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/756,014. Although the conflicting claims are not identical, they are not patentably distinct from each other because both groups of claims disclose a surgical ablation instrument with either a loop or disposable ablation element.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/756,645. Although the conflicting claims are not identical, they are not patentably distinct from each other because both groups of claims disclose a surgical ablation instrument with either a loop or disposable ablation element.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments filed 6-8-07 have been fully considered but they are not persuasive. Edwards 6,056,744 col. 8:33-51 represents a common principle in the electrosurgical arts. (This principle is not limited to this patent and can be shown in other patents.) The principle maintains that energy types (microwave, light, RF, ultrasound, fluid) are seamlessly interchangeable and obvious in light of each other.

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This principle provides the basis for this obviousness rejection. The principle is also a valid defense to *In re Ratti* as argued by the Applicant.

It is also noted that this principle is articulated in the Applicant's own dependent claims in this family of four applications. 10/756,660; 10/756,717; 10/756,645; 10/756,014. See claims 5-10 in 10/756,014.

The Applicant provides *In re Ratti* to argue against the obviousness of changing energy application type of the asserted prior art (which is the gist of the current obviousness rejections, above). The Office provides in response, Edwards 6,056,744 col. 8:33-51 to prove that in the electrosurgical arts (the field in which the instant application belongs) interchangeability between different energy application types is commonplace and seamless unlike what the Applicant alleges in his *In re Ratti* arguments. To this end, the Office maintains the position that the prior art makes obvious the currently claimed invention. Furthermore, the Examiner respectfully asserts that the independent claim(s) are currently too brief and broad. A telephone interview might be of benefit for this application and the three related applications listed at the top of this Office Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

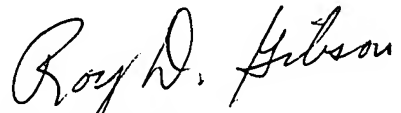
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Pete Vrettakos  
August 18, 2007



ROY D. GIBSON  
PRIMARY EXAMINER